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Toxicological Assessment Protocol for Encapsulants Pursuant to Proposed Regulation 105 CMR 460.115: Process for Approval of Encapsulants for the Abatement of Lead Paint

1.0 BACKGROUND:

The Massachusetts Department of Public Health Childhood Lead Poisoning Prevention Program (CLPPP) has developed an application package for encapsulant manufacturers to submit to the designated certification organization for review and approval of an encapsulant for use as an lead abatement method in Massachusetts.

The application package includes product performance characteristics; applicator, property-owner, and tenant literature; and hazard information. Copies of product material safety data sheets, labels, and associated documentation must accompany the application package. The information provided on the toxicity of the product will be reviewed as part of the certification process.

The intent of this toxicological review is not to mandate further research on the product, but to ensure that sufficient information is available to provide adequate and appropriate hazard warnings about the product.

This assessment will determine human health risk for repeated or one-time exposures associated with the encapsulant product during preparation, application, curing, and fully cured states.

2.0 TOXICOLOGICAL ASSESSMENT DOCUMENTATION:

2.1 Material Safety Data Sheet (MSDS) for encapsulant product.

a. Written within the last two years of date of application and complies with OSHA Hazard Communication Standard, 29 CFR 1910.1200 (g).
b. All ingredients and concentrations must be listed, including chemical formula as described in the OSHA Hazard Communication Standard, 29 CFR 1910.1200 (g)(A), (B), and (C);
c. Consideration of trade secrets or proprietary formulations will be made as provided under the OSHA Hazard Communication Standard, 29 CFR 1910.1200 (i) and Appendix D of the standard. This includes the signing and execution of a confidentiality agreement between the encapsulant manufacturer and the designated certification organization. The designated certification organization will be the sole custodian of the confidential information.

2.2. Toxic Substance Control Act (TSCA) status.

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2.3 Product label that complies with OSHA Hazard Communication Standard, 29 CFR 1910.1200, or if the product is found to be eligible for general consumer use, then the label must comply with regulations of the U.S. Consumer Product Safety Commission, 16 CFR Part 1500.

2.4 Product information insert:

a. Contains the material safety data sheet; and
b. Product use and disposal directions for applicator, property-owner, and tenant.

3.0 RESTRICTIONS:

Encapsulants containing chemicals or mixtures that are found on the following lists will undergo careful scrutiny:

3.1 A "select carcinogen," as described in the OSHA Occupational Exposure to Hazardous Chemicals in Laboratories Standard, 29 CFR 1910.1950, which includes:

a. a carcinogen regulated by the Occupational Safety and Health Administration (OSHA) or listed by the American Conference of Governmental Industrial Hygienists (ACGIH);
b. listing under the category "known to be carcinogens," in the latest edition of the Annual Report on Carcinogens published by the National Toxicology Program (NTP);
c. listing under Group 1, "carcinogenic to humans," by the latest edition of the International Agency for Research on Cancer Monographs (IARC);
d. listing in either Group 2A or 2B by IARC or under the category "reasonably anticipated to be carcinogens," by NTP, and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria:

1. After inhalation exposure of 6-7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m^3;
2. After repeated skin application of less than 300 mg/kg of body weight per week; or
3. after oral dosages of less than 50 mg/kg of body weight per day.

3.2 Superfund Amendments and Reauthorization Act (SARA) Title 313 Extremely Hazardous Chemicals List.

3.3 EPA's 33/50 Program which includes 17 targeted chemicals. These include benzene, cadmium and compounds, carbon tetrachloride, chloroform, chromium and compounds, cyanides, dichloromethane, lead and compounds, mercury and compounds,

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methyl ethyl ketone, methyl isobutyl ketone, nickel and compounds, tetrachloroethylene, toluene, trichloroethane, trichloroethylene, and xylene(s).

3.4 Ozone depleting chemicals as described in the 1987 Montreal Protocol

3.5 Priority Toxic Water Pollutants.

4.0 WRITTEN RECOMMENDATION BY TOXICOLOGIST:

A toxicologist certified by the American Board of Toxicology will review the toxicological information provided and utilize available databases. The toxicologist will provide a written recommendation to the CLPPP regarding the potential human health hazards associated with the encapsulant product during preparation, application, curing, and fully cured states. This will include recommendations regarding occupancy during and after application of a particular encapsulant.